COLORADO MEDICAID P&T COMMITTEE MEETING MINUTES

July 8, 2014

Members Present | **Medicaid Pharmacy Department**

Lynn Parry, MD
Shilpa Kinikar, PharmD, BCPS
Neil Stafford, MD
Roy J. Durbin Jr., MD
Kimberly Nordstrom, MD, JD
Patricia Lanius, Rph

Robert Lodge, PharmD
Swaniee Grubb, PharmD
Kelli Metz, PharmD

Members Absent
Jennifer Hyer, MD
Leslie Moldauer, MD, MBA
Katy Trinkley, PharmD
David Fox, MD
Irene Girgis, PharmD

GENERAL ORDERS and NEW BUSINESS

The meeting of the CO Medicaid P&T Committee was held on July 8, 2014 at 225 E. 16th Ave., 1st Floor Conference Room, Denver, Colorado. A quorum being present, K. Nordstrom officially called the meeting to order at 13:09.

K. Nordstrom asked for approval of the minutes from the April 8, 2014 meeting. L. Parry motioned to approve and S. Kinikar seconded. The minutes were approved with no audible dissent.

UNFINISHED BUSINESS

S. Grubb gave an update on the PDL changes for the following:

- Newer generation antihistamines and combinations
- Angiotensin receptor blockers
- Renin inhibitors and combinations
- Fibromyalgia agents
- Testosterone products
- Long acting oral opioids
- Inhaled anticholinergics and combinations
- Inhaled beta 2 agonists
- Inhaled corticosteroids and combinations
- Skeletal muscle relaxants

- Topical immunomodulators

NEW BUSINESS

S. Grubb gave updates about the prior authorization helpdesk call statistics. The prior authorization numbers from the previous month were about the same as usual. This being about 87% approvals and 13% denials.

S. Grubb spoke of 2 client representative openings and requested resumes/CV from anyone interested.

K. Nordstrom presented guidelines for manufacturer and public presentations. Oral presentations will be restricted to products that are being reviewed for PDL status. Presentations will be limited to a maximum of three minutes per representative per drug product. Representatives will be called to present in the order in which they signed in by drug class. Presentations must be limited to verbal comments. No visual aids, other than designated handouts, are permitted. Presentations should follow the one page summary that was submitted to the Department. The audience will be considered a reference tool for the committee. The committee will discuss topics and audience participation will be allowed if P&T members ask for clarification. S. Grubb disseminated recently received public comments to the committee members.

K. Nordstrom moved to discuss the hepatitis C agents. N. Steinfurth from Hep C Connection spoke regarding Sovaldi. She had a letter from Dr. Everson stating his experiences with treatment. Dr. Clark Cooley also wrote a letter. S. Kinikar asked for a breakout of Dr. Everson treatments. N. Stafford asked about prior authorization adherence but there were no comments. Michelle Puyear from Gilead spoke regarding Sovaldi. She provided evidence from EASL meeting regarding durability of 210 patient's from NEUTRINO that stayed in the registry and 100% of these reached SVR. Laura Litzenberger from Janssen spoke regarding Olysio. S. Grubb provided utilization, FDA updates, and current preferred products. S. Grubb provided the Department history with Sovaldi. There was discussion regarding the lack of head to head studies and profile safety concerns, at least one protease inhibitor should be preferred keeping the above concerns in mind. S. Kinikar and K. Nordstrom discussed if they want to prefer simeprevir. N. Stafford is concerned about the comparison of these with the lack of data. P. Lanius spoke about the reported side effects. K. Nordstrom still wants to talk about side effects. S. Kinikar made a motion that although there is a lack of head to head studies both boceprevir and teleprevir have significant reported side effects and drug-drug interactions. P. Lanius seconded. The motion passed with no audible dissent. R. Durbin made the motion that during the course of the prior authorization the question should be asked does the licensed provider have expertise or consulted with an expert in treating hepatitis C. S. Kinikar seconded. Motion passed with no audible dissent. P. Lanius made the motion that based on very recent FDA approval and limited published

studies, the recommendation would be prior authorization criteria until more information is available. L. Parry seconded. The motion passed with no audible dissent.

K. Nordstrom moved to discuss the oral anticoagulants. William O'Neil from Boehringer Ingelheim spoke about Pradaxa. The FDA is looking at a new study versus warfarin that showed lower risk of ischemic stroke, intracranial hemorrhage, and death. However, a similar risk of myocardial infarction and increased risk of major bleed. He spoke of a black box with real world data from the department of defense that looked at new starts on both and looked at risks and healthcare costs. Diana Dills from Pfizer spoke about Eliquis. It has a new indication for DVT/VTE for hip and knee surgery. The ADVANCE trial showed less bleeding compared to enoxaparin and asked for parity. There is also a new dosing recommendation for patients with ESRD on dialysis. Laura Litzenberger spoke regarding Xarelto. It is the only daily dosed new oral anticoagulant. It is the only one with treatment of DVT/VTE/PE (therapy then maintenance). It has a new partial reversal with prothrombin complex concentrate (PCC) that was studied on 12 patients in a phase 1 trial. S. Grubb provided utilization, FDA updates, and current preferred products. P. Lanius asked about the coverage of LMWH's and S. Grubb explained there are no limits. R. Durbin states he uses a lot of anticoagulants and referrals from specialists that say Xarelto has less bleeding. N. Stafford states there is not enough comparative evidence. L. Parry says fixed dosing is probably the best benefit and is very appropriate for some. She spoke of compliance and access issues for some with warfarin. P. Lanius made the motion of in addition to warfarin keeping preferred drug status, at least one NOAC be considered for inclusion based on indication of treatment as well as prevention. R. Durbin seconded. The motion was withdrawn. K. Nordstrom said with current available studies that all three agents appear to have similar safety profiles however S. Kinikar did not know if we can say that. N. Stafford made the motion that we recommend warfarin remain preferred. S. Kinikar seconded. The motion passed with no audible dissent. N. Stafford made the motion we recommend one of the NOAC be placed on preferred status based on marginally better efficacy for non valvular atrial fibrillation compared to warfarin. L. Parry seconded. The motion passed with no audible dissent.

K. Nordstrom moved to discuss the bisphosphonates. With no speakers being present S. Grubb provided utilization, FDA updates, and current preferred products. S. Kinikar made the motion that DUR place a limit of no more than 5 years, unless otherwise indicated requiring bisphosphonate therapy. L. Parry seconded. The motion passed with no audible dissent. S. Kinikar made the motion that at least on agent for daily, weekly, and monthly dosing be available as well as an agent in liquid form and etidronate for spinal cord injuries. P. Lanius seconded. The motion passed with no audible dissent.

K. Nordstrom moved to discuss the oral biguanides. With no speakers being present S. Grubb gave FDA updates, utilization, and current preferred products. R. Durbin discussed that hypoglycemia has been discussed more lately with patients starting insulin, that safety is an issue that should be monitored and that it is still a mainstay and should be available. L.

Parry made the motion to include as preferred both and extended and sustained release agent in at least 500mg. S. Kinikar seconded. The motion passed with no audible dissent.

K. Nordstrom moved to discuss the hypoglycemic combinations. With no speakers being present S. Grubb gave FDA updates, utilization, and current preferred products. S. Kinikar made the motion to prefer none of the combination products. L. Parry seconded. Motion passed with no audible dissent.

K. Nordstrom moved to discuss meglitinides. With no speakers being present S. Grubb gave FDA updates, utilization, and current preferred products. P. Lanius made the motion to keep both products non-preferred. L. Parry seconded. The motion passed with no audible dissent.

K. Nordstrom moved to discuss newer diabetic agents. William O Neil from Boehinger Ingelheim spoke about Tradjenta. Mike Ketcher from Merck spoke of Januvia. Laura Litzenberger from Janssen spoke of Invokana stating its non-inferior to sitagliptin and does increase LDL but not the ratio. Kyle Peters from NovoNordisk spoke of Victoza stating it had superior A1C reduction compared to Byetta and also showed superiority in safety to Byetta. S. Grubb gave FDA updates, utilization information, and current preferred products. R. Durbin states the data has changed to not support metformin to be used first line. R. Durbin made the motion that we recommend DUR review the requirement of metformin prior to other classes. P. Lanius seconded. The motion passed with no audible dissent. Discussion about Victoza has been shown to be more effective than Byetta, has better safety profile, and decreased side effects compared to Byetta and should be the preferred. Studies have shown Victoza shows superior to Byetta in A1C and FBG. Victoza 1.8mg has a 1.4% reduction in A1C and Bydureon had a 1.28% reduction. R. Durbin made the motion that one GLP 1 should be preferred with a friendly amendment by P. Lanius to at least one. S. Kinikar seconded. The motion passed with no audible dissent. R. Durbin made the motion that Victoza is a once daily medications and appears to be superior to Byetta in currently available limited studies. S. Kinikar seconded. The motion passed with one abstention. L. Parry made the motion to have one DPP-4 and one GLP-1, with consideration given to renal dosing and renal insufficiency preferred. S. Kinikar seconded. The motion passed with no audible dissent.

K. Nordstrom moved to discuss thiazolidinediones. With no speakers present S. Grubb gave FDA updates, utilization information, and current preferred products. R. Durbin stated that Actos actually increases fluid retention but was found overall to be cardio protective and overall mortality was decreased. He felt that Actos should be available to address insulin resistance. R. Durbin made the motion to recommend that one thiazolidinedione be preferred secondary to the REMS removal. S. Kinikar seconded. P. Lanius made a friendly amendment that secondary to REMS removal we recommend one thiazolidinedione be preferred. N. Stafford seconded. The motion passed with one nay.

K. Nordstrom moved to discuss erythropoiesis stimulating agents. With no speakers being present S. Grubb gave FDA updates, utilization information, and current preferred products. S. Kinikar made the motion to recommend that at least one agent with pediatric indications is selected as preferred. L. Parry seconded. The motion passed with no audible dissent.

K. Nordstrom moved to discuss over active bladder agents. With no speakers present S. Grubb gave FDA updates, utilization information, and current preferred products. P. Lanius made the motion that one immediate-release drug, one extended release drug, and one for use in pediatrics down to age five years should be given preference on the preferred drug list. S. Kinikar seconded. The motion passed with no audible dissent. S. Kinikar made the motion that because of new safety information about Vesicare it should not be preferred. With a statement that Vesicare is being studied post market for concerns with cardiovascular events. P. Lanius seconded. The motion passed with no audible dissent.

K. Nordstrom moved to discuss stimulants and ADHD. Tim Hartman from Pfizer spoke regarding Quillivant XR. S. Grubb gave FDA updates, utilization information, and current preferred products. L. Parry made a motion to include at least one liquid, on capsule, and one sprinkle for both the ER and IR forms of methylphenidate and amphetamine. S. Kinikar seconded. The motion passed with no audible dissent. L. parry made the motion that one alpha 2 adrenergic agonist be available as a preferred drug. S. Kinikar seconded. The motion passed with no audible dissent.

Adjourn at 16:45.

By: _____
Kimberly Nordstrom, MD, Chair

Date: _____